

PRIOR AUTHORIZATION POLICY

Attention Deficit/Hyperactivity Disorder (ADHD) Agents

To Initiate a Coverage Review, Call 1-800-417-1764

Drugs Affected:

- Adderall[®] (dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine sulfate, amphetamine aspartate immediate-release tablets – Teva, generics)
- Adderall XR[®] (mixed amphetamine salts [dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine sulfate, amphetamine aspartate] extended-release capsules – Shire US, generics)
- Concerta[®] (methylphenidate extended-release tablets – Janssen, generics)
- Daytrana[®] (methylphenidate transdermal system – Noven Pharmaceuticals)
- Desoxyn[®] (methamphetamine tablets – Recordati, generics)
- Dexedrine[®] (dextroamphetamine sulfate tablets – Amedra Pharmaceuticals, generics)
- Dexedrine[®] Spansules[®] (dextroamphetamine sustained-release capsules – Amedra Pharmaceuticals, generics)
- Evekeo[™] (amphetamine sulfate tablets – Arbor Pharmaceuticals)
- Focalin[®] (dexmethylphenidate immediate-release tablets – Novartis, generics)
- Focalin[®] XR (dexmethylphenidate extended-release capsules – Novartis, generics)
- Metadate[®] CD (methylphenidate extended-release capsules – UCB)
- Metadate[®] ER (methylphenidate sustained-release tablets – UCB, generics)
- Methylin[®] (methylphenidate tablets, chewable tablets, and oral solution – Shionogi, generics [tablets and oral solution only])
- methylphenidate extended-release capsules (generics to discontinued Methylin[™] ER)
- Procentra[®] (dextroamphetamine sulfate liquid – FSC Laboratories, generics)
- Quillivant[™] XR (methylphenidate extended-release oral suspension – Pfizer)
- Ritalin[®] (methylphenidate immediate-release tablets – Novartis, generics)
- Ritalin[®] LA (methylphenidate extended-release capsules – Novartis, generics)
- Ritalin SR[®] (methylphenidate sustained-release tablets – Novartis, generics)
- Strattera[®] (atomoxetine capsules – Eli Lilly and Company)
- Vyvanse[®] (lisdexamfetamine dimesylate capsules – Shire US)
- Zenzedi[™] (dextroamphetamine tablets – Arbor Pharmaceuticals)

OVERVIEW

All of the central nervous system (CNS) stimulants are indicated for the treatment of attention deficit/hyperactivity disorder (ADD/ADHD).^{1-18,46} Dextroamphetamine sulfate tablets, Zenzedi, and Adderall (generics) are indicated in patients ≥ 3 years of age; the other products are indicated in patients ≥ 6 years of age. Adderall XR (generics), Vyvanse, Concerta (generics), and several methylphenidate products are indicated for use in adults with ADHD. Several products are also indicated for the treatment of narcolepsy. Evekeo and methamphetamine tablets are also indicated as adjunctive therapy for the short-term (i.e., a few weeks) treatment of exogenous obesity.^{4,50} However, guidelines on the management of obesity do not address or recommend use of amphetamine or methamphetamine (or any other ADHD stimulants).⁴²⁻⁴⁴ The limited usefulness of amphetamines should be weighed against

possible risks inherent in use of the drugs. Vyvanse is the only stimulant medication indicated for the treatment of binge eating disorder.⁵

Strattera, a non-stimulant medication, is indicated for the treatment of ADHD in children ≥ 6 years of age, adolescents, and adults.⁵¹

POLICY STATEMENT

Coverage is provided immediately (without generating a coverage review process) for CNS stimulants and Strattera for patients 5 years of age and older (up to their 18th birthday), unless specified below. Coverage for Daytrana and Vyvanse is provided immediately (without generating a coverage review process) for patients 6 years of age and older (up to their 18th birthday). For certain CNS stimulants, coverage is provided for any patient, regardless of age, if their claims history includes drugs used in the treatment of multiple sclerosis. Determination of coverage for all other claims not meeting the aforementioned criteria is determined through a prior authorization process. All approvals are provided for 12 months in duration unless otherwise noted below.

AUTHORIZATION CRITERIA

A. Coverage is provided for Adderall, mixed amphetamine salts, Dexedrine and dextroamphetamine for use in patients ≥ 3 years of age. Coverage for all other agents in patients naïve to therapy is provided in patients who are ≥ 4 years of age.

B. Long-term combination therapy (i.e., >2 months) with atomoxetine (Strattera) and a CNS stimulant is not covered. Coverage for ≤ 2 months for Strattera with a CNS stimulant is provided to allow for titration to monotherapy with the desired drug.

C. Coverage of ADHD medications is provided for those who meet the following criteria:

1. Attention Deficit/Hyperactivity Disorder (ADD/ADHD)

Diagnosis of ADHD must be confirmed using established criteria (for example, such as the current Diagnostic and Statistical Manual of Mental disorders (DSM-IV), DSM-IV based ADHD rating scales such as Conners Comprehensive Behavior rating scale or ADHD rating scale IV, or other clinical criteria) in patients naïve to therapy with the requested medication.

2. Binge Eating Disorder

Approve only Vyvanse if the patient meets BOTH of the following criteria (A and B):

A) The patient is ≥ 18 years old; AND

B) The patient has tried one of the following medications (i.e., SSRI [citalopram, escitalopram, fluoxetine, paroxetine, sertraline], imipramine, topiramate, zonisamide) for binge eating disorder.

D. Coverage of ADHD medications (except Daytrana, Strattera, Vyvanse) is provided for the below additional approved indications.

1. Narcolepsy

Prescriber must confirm that the patient does not have underlying conditions that may contribute to excessive sleepiness (e.g., nocturnal myoclonus, current drug therapy that affects sleep or contributes to daytime sedation, or chronic voluntary or involuntary sleep deprivation through shift work).

2. Idiopathic Hypersomnolence

Confirmed by polysomnography where excessive sleepiness is not due to other sleep disorders, such as narcolepsy, obstructive sleep apnea or posttraumatic hypersomnia.

3. Fatigue associated with Multiple Sclerosis (MS)

4. Treatment for Depression – Approve for 6 weeks

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2. Adderall XR® [prescribing information]. Wayne, PA: Shire US Inc.; December 2013.
3. Dexedrine® Spansule® and tablets [prescribing information]. Horsham, PA: Amedra Pharmaceuticals LLC; October 2013.
4. Desoxyn® [prescribing information]. Lebanon, NJ: Recordati Rare Diseases Inc.; December 2013.
5. Vyvanse® capsules [prescribing information]. Wayne, PA; Shire US Inc. January 2015.
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7. Metadate® CD capsules [prescribing information]. Smyrna, GA: UCB, Inc; December 2013.
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POLICY IMPLEMENTATION/REVISION INFORMATION

Prior Authorization

Original Implementation Date: 11/1/2010

Revision Information:

April 2015	Update policy to ESI format. Add new approval indication of binge eating disorder for Vyvanse. New medication, Evekeo, added to the policy.
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